(12) UK Patent Application (19) GB (11) 2 188 418 (13) A

(43) Application published 30 Sep 1987

(21) Application No 8607660

(22) Date of filing 27 Mar 1986

(51) INT CL⁴
B01L 3/00 // G01N 33/543

(52) Domestic classification (Edition I):
G1B 602 609 614 615 GB CC
U1S 1296 G1B

(56) Documents cited

GB A 2063470	GB 1571872	EP A2 0042755
GB 1603771	GB 1562957	US 4146365

(58) Field of search
G1B
Selected US specifications from IPC sub-classes B01L G01N

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(54) Assay tray assembly

(57) An assay tray assembly includes a base tray having a plurality of reaction wells 13 and one or more overlying trays 20 each having a plurality of reaction projections 23 to extend into the reaction wells respectively. In immunoassay, the reaction wells and the reaction projections can be incubated simultaneously for detecting two or more specific substances present in a specimen which is introduced into the reaction wells.

The projections 23 may be hollow or solid truncated-cone-shaped. The assembly may include an indented support plate 10 (Fig. 7) for the base tray.

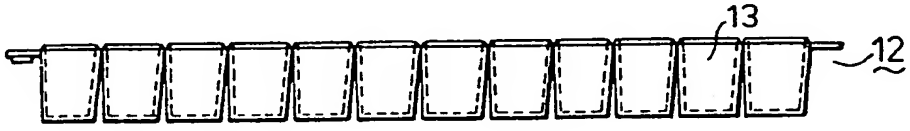

FIG. 4

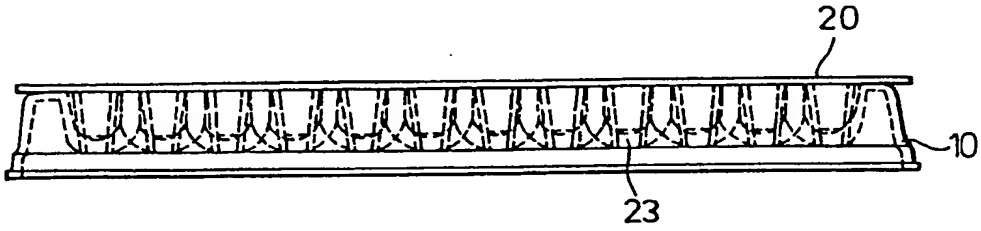

FIG. 7

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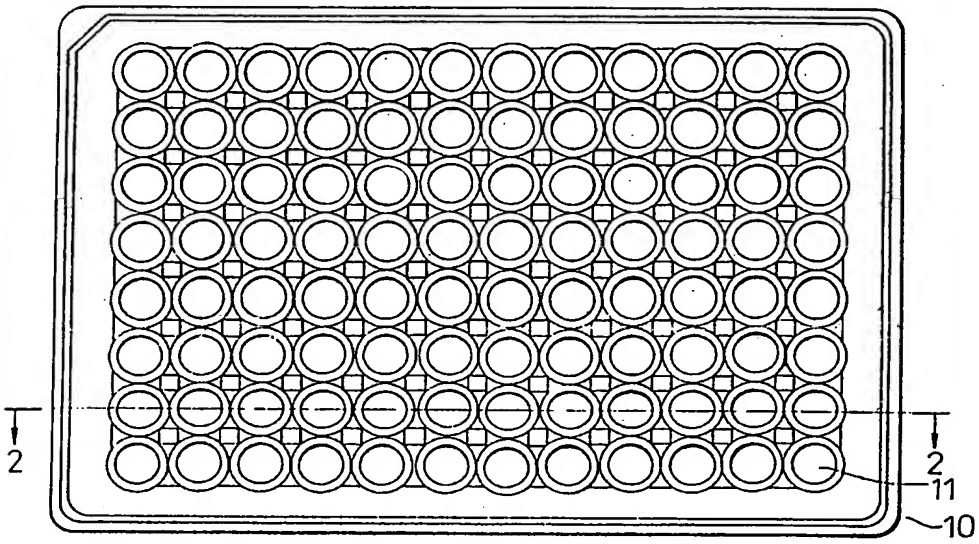

FIG. 1

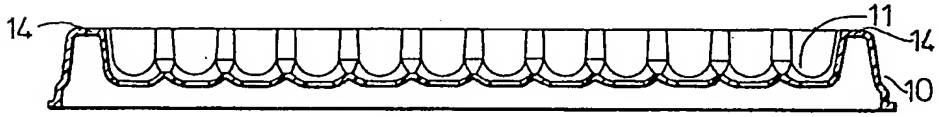

FIG. 2

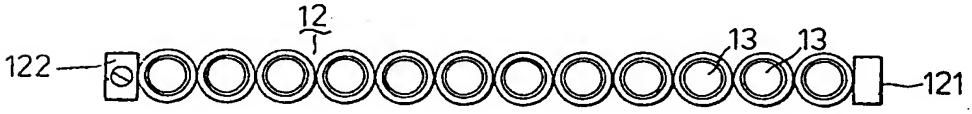

FIG. 3

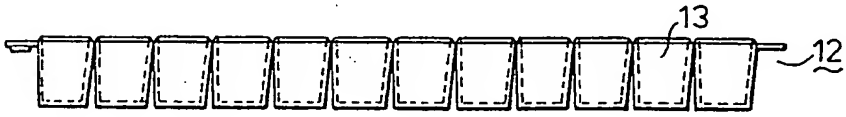

FIG. 4

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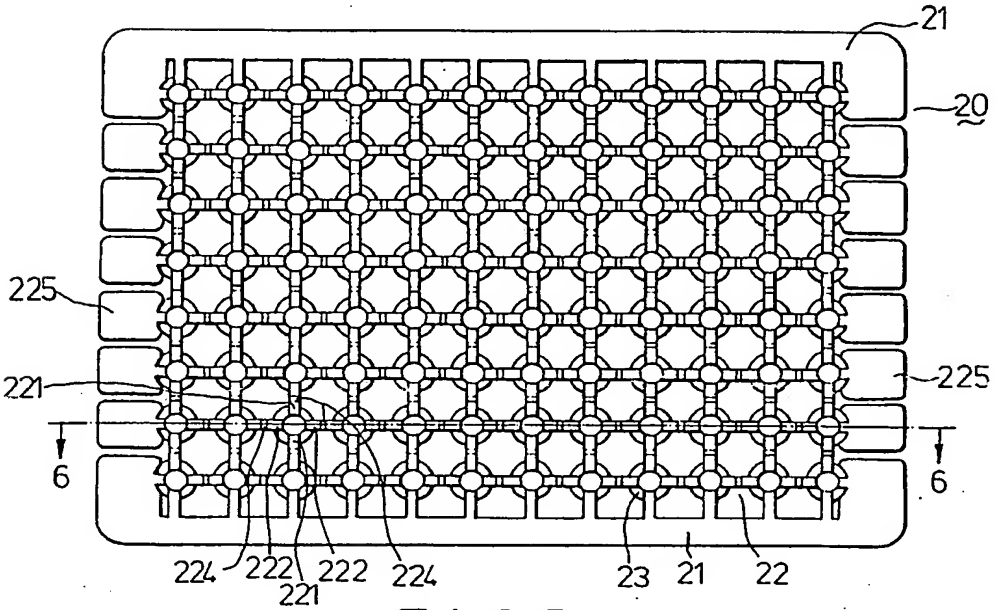

FIG. 5

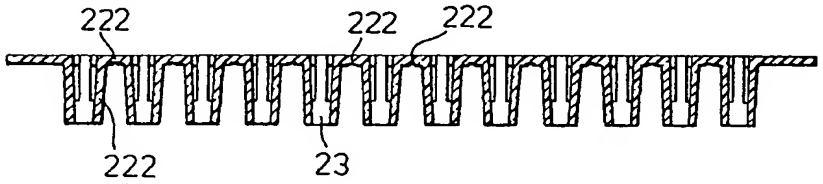

FIG. 6

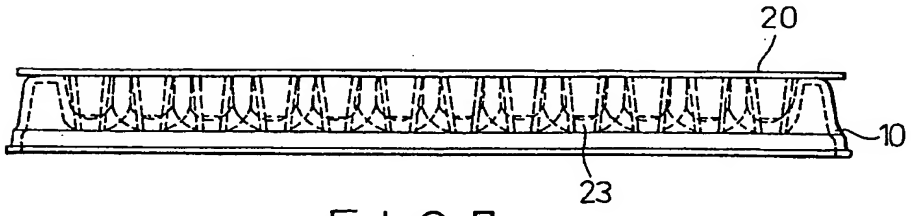

FIG. 7

SPECIFICATION

Improved assay tray assembly

This invention relates to a diagnostic assay device used for performing numbers of routine tests simultaneously, and particularly to an improved assay tray assembly constituted of a base assay tray with a plurality of reaction wells and an overlying tray having reaction projections extending into the reaction wells, the inner surface of each reaction well and the outer surface of each reaction projection in each reaction well being used for incubation.

Assay trays are commonly used in immunoassays, for instance, for the determination of the presence of a specific substance, such as, an antigen contained in serun or plasma. A typical assay tray includes a number of reaction wells each receiving a reaction bead for incubation. Such a tray can be used for performing a number of routine tests simultaneously on a specimen so as to detect a specific antigen, for instance, Hepatitis B Surface antigen. During the tests, each reaction well gives an incubated substance on the incubated reaction bead for examination. However, if it is desired to detect in the same specimen the presence of another antigen, for instance, Hepatitis B e antigen, another assay tray will be needed to perform on the specimen additional tests of similar procedures, and therefore, an additional amount of the specimen and additional time is needed for the second determination.

It is an object of the invention to provide a novel assay tray assembly that can provide two or more than two different incubation surfaces in each reaction well so that each reaction well will give different incubated substances simultaneously.

Another object of the invention is to provide an assay tray assembly with which two or more antigens in a specimen of serum or plasma can be determined in less time with a reduced amount of specimen.

The invention provides an assay tray assembly which includes a base tray member having a plurality of non-communicating reaction wells opening at the top side thereof, and an overlyig tray member which lies over the base tray member and has a plurality of first reaction projections extending downwardly from the bottom side thereof into the wells respectively. The reaction projctions are smaller in cross-section than the reaction wells and are capable of extending respectively into the wells without contacting the inner surfaces of the wells. The inner surface of the reaction wells and the surface of the hollow reaction projections can be coated respectively with two different reaction substances, such as antigens or antibodies, for incubation. The incubated reaction projections can be removed from the incubated wells by separating the overlying tray and the base tray so that the incubated reaction projections and reaction wells can undergo examination separately to determine the respective results.

In one aspect of the invention, the assay tray assembly includes a tray-shaped support plate having a plurality of indent seats arranged in intersecting rows, and a plurality of cup members which form reaction wells and are arranged into a plurality of groups, the cup members in each group being of one-piece with each other and respectively seated detachably on each row of the indented seats of the support plate.

The overlying tray member is a one-piece construction having reaction projectins arranged in intersecting rows and a network of ribs interconnecting the reaction projections. The ribs are provided with seams through which the reaction projections can be separated easily into individual parts.

The present exemplary preferred embodiment will be described in detail with reference to the following drawings.

Figure 1 is a plan view of a tray-shaped support plate of the assay tray assembly according to the present invention;

Figure 2 is a sectional view taken along line 2–2 of Fig. 1;

Figure 3 is a plan view of a strip of cup members;

Figure 4 is an elevation view of the cup members of Fig. 5;

Figure 5 is a plan view of an overlying tray according to the present invention;

Figure 6 is a sectional view of the overlying tray taken along line 6–6 of Fig. 5; and

Figure 7 is an elevation view of the assembly of the support plate, cup members and the overlying tray member.

According to the present invention, the base tray of an assay tray assembly has a plurality of non-communicating reaction wells opening at the top side thereof and arranged in intersecting rows. Preferably, the base tray conforms to a conventional microtiter plate or the like. The overlying tray member of the tray assembly includes the same number of reaction projections extending downward respectively into the reaction wells from the bottom side of the overlying tray member. The cross-section of each reaction projection is smaller than that of the corresponding reaction well so that it does not contact the inner surface of the reaction well. The inner surface of the side wall of each reaction well and the surface of each reaction projection are subjected to surface-roughing treatment to enhance the reaction area thereof, whereas the inner surface of the bottom side of each reaction well remains be smooth and transparent. The reaction projections can be a truncated-cone-shaped body of either solid or hollow construction.

Alternatively, the tray assembly may include

two or more than two overlying trays. In a preferred embodiment of the tray assembly which has two overlying tray members, the reaction projections of the first overlying tray are in a hollow truncated-cone shape, and the reaction projections of the second overlying tray are in a solid truncated-cone shape and smaller in cross-section than the hollow reaction projections of the first overlying tray. The first overlying tray is superimposed on the base tray with its hollow reaction projections extending into the reaction wells of the base tray, and the second overlying tray is superimposed on the first overlying tray with its solid reaction projections extending into the hollow reaction projections of the first overlying tray.

In a still further alternative embodiment of the assay tray assembly, the base tray and the overlying tray are constructed in such a manner that the reaction wells and the reaction projections can be separated individually by cutting or clipping the base tray and the overlying tray. An example of this type is shown in Figs. 1 through 6, wherein a base tray includes a tray-like support plate 10 having 8 × 12 indented seats 11 arranged in intersecting rows. Eight separate strip members 12 are provided to be superimposed on the support plate 10. Each strip member 12 is a one-piece construction having a row of twelve cup members 13 interconnected side by side at their tops to be seated on each row of the indent seats 11 of the support plate 10. Each strip member 12 has two top flanges 121 at two ends thereof to rest on two opposite raised bordering sides 14 of the support plate 10. Each strip member 12 can be removed easily from the support plate 10, and each cup member 13 forms a reaction well and can be separated from the adjacent cut members 13 by being cut or clipped.

There is an overlying tray member 20 to be superimposed on the strip members 12 lying on the support plate 10. The overlying tray member 20 has two opposite bordering sides 21 and a one-piece molded network 22 of ribs extending between the two bordering sides 21 and interconnecting 8 × 12 reaction projections 23 arranged in intersecting rows. The network 22 includes a pair of first opposing rib limbs 221 and a pair of second opposing rib limbs 222 which extend upwardly from each reaction projection 23 and then turn 90 degrees to extend radially. Between each two first adjacent limbs 221 and between each two second adjacent limbs 222 are provided seams 224 by which each reaction projections 23 can be separated from each other simply by breaking the rib limbs 221 and 222. End flaps 225 are provided at the endmost limbs 222.

It can be appreciated that, by using the tray assembly according to the present invention, the amount of specimen and the time required for detecting two antigens in a specimen can be reduced, since the incubation for the two determination is carried out simultaneously. The use of the assay tray assembly 1 will be described in detail in the following examples:

EXAMPLE 1

Enzymatic Immunoassays to detect Hepatitis B Surface Antigen (HBsAg) and Hepatitis B e Antigen (HBeAg) in Serum or plasma

One tenth ml of a test sample is pipetted into one of the reaction wells, receiving the reaction projections of the overlying tray. The inner surface of the reaction well and the outer surface of the reaction projection are coated with antibodies to HBsAg and HBeAg respectively. One tenth ml of Negative Control is pipetted into each of three designated wells, and 0.1 ml of HBsAg Positive Control and 0.1 ml of HBeAg Positive Control are pipetted respectively into two another wells. The base tray and the overlying tray are covered with a cover sealer and the reaction wells are incubated in a water bath at 40°C for 2 hours. Afterwards, the cover sealer is removed and the content of each well is then washed away.

A mixture containing horse radish peroxidase-labelled antibodies to HBsAg and HBeAg is added to each of the above wells 11 in an amount of 0.1 ml. The tray assembly is covered again with a cover seal and the reaction wells are incubated in the water bath at 40°C for 2 hours.

After incubation, the cover seal is removed, and the overlying tray is separated from the reaction base tray and rinsed by means of a washing device. The overlying tray is then superimposed on a new base tray of which the wells are not coated. The contents in the reaction wells of the base tray are removed by suction and the base tray is rinsed with the washing device.

Then, 0.1 ml of O-phenylene diamine is added into each well of the former and latter base trays, and the contents in the wells are are kept there for one half hour. Afterwards, 0.1 ml of 2N sulfuric acid is added into each well 11. The results concerning HBsAg and HBeAg are determined by naked eye or spectrophotometer at the wavelength of 492 nm.

EXAMPLE 2

A radioimmunoassay to detect Hepatitis B Surface Antigen and Hepatitis B e Antigen.

One tenth ml of the test sample is pipetted into one of the wells of the tray assembly. 0.1 ml of negative control is pipetted into each of three designated wells and 0.1 ml of positive control is pipetted into each of two designated wells. The contents in the wells are incubated in a water bath at 40°C for two hours. The reaction wells are coated with anti-HBs and the reaction projections are coated with anti-HBe. Since each well 11 and each hollow member 21 has to be examined indivi-

dually, both base tray and overlying tray should be of the type that can be cut or clipped for separating the reaction wells and the reaction projections.

After the end of the incubation period, the contents of the wells are washed away, and 0.1 ml of a mixture containing ^{125}I-anti-HBs, ^{125}I-anti-HBe, is added into each well, and the tray assembly is incubated in the water bath at 40°C for two hours. The reaction projections are removed from the wells by separating the overlying tray from the base tray. The overlying tray is then rinsed by a washing device, and the reaction projections are separated individually. Each reaction projection is replaced in an appropriate assay tube, and the results concerning HBeAg are determined by means of a well-type gamma scintillation counter.

The contents in the reaction wells of the base tray is removed by aspiration and the base tray is rinsed by a washing device. Afterward, the base tray is clipped into separate reaction wells which are then put into appropriate assay tubes for determining the results concerning HBsAg by means of a well-type gamma scintillation counter.

CLAIMS

1. An assay tray assembly comprising:

a base tray means having a plurality of non-communicating reaction wells opening at the top side thereof; and

a first overlying tray member which lies over the base tray means and has a plurality of first reaction projections extending downwardly from the bottom side of the overlying tray member, the reaction projections being smaller in cross-section than the reaction wells and capable of extending respectively into the reaction wells of the base tray means.

2. An assay tray assembly as claimed in Claim 1, wherein the inner surface of the side wall of each of the reaction wells and the outer surface of each of the first reactions projections are subjected to surface-treatment to enhance the reaction area.

3. An assay tray assembly claimed in Claim 1, wherein each of the first reaction projections is a truncated-cone-shaped solid body.

4. An assay tray assembly as claimed in Claiim 1, wherein each of the first reaction projections is a truncated-cone-shaped hollow body having a through-hole extending from the bottom to the top of the overlying tray.

5. An assay tray assembly as claimed in Claim 4, further including a second overlying tray member which lies on the first overlying tray member and which has a plurality of second reaction projections extending downward respectively into the truncated-cone-shaped hollow bodies of the first overlying tray from the bottom side of the second overlying tray member, the second reaction projections being smaller in cross-section than the first reaction projections.

6. An assay tray assembly as claimed in Claim 1, wherein the base tray means includes a tray-shaped support plate having a plurality of indented seats arranged in intersecting rows, and a plurality of cup members which form reaction wells and are arranged into a plurality of groups, the cup members in each group being of one piece with each other and respectively seated detachably on the indented seats in each row.

7. An assay tray assembly as claimed in Claim 1, in which the first reaction projections are arranged in intersecting rows, wherein the first overlying tray member is a one-piece construction having a network of ribs interconnecting the first reaction projections, the ribs being provided with seams through which the first reaction projections can be separated easily into individual parts.

8. An assay tray assembly as substantially described hereinbefore with reference to the accompanying drawings.

Printed for Her Majesty's Stationery Office
by Burgess & Son (Abingdon) Ltd, Dd 8991685, 1987.
Published at The Patent Office, 25 Southampton Buildings,
London, WC2A 1AY, from which copies may be obtained.